Reference number(s)
2111-A

JURISDICTION SPECIFIC MEDICARE PART B

Intravenous Immune Globulin (IVIG):

Asceniv, Bivigam, Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Octagam, Panzyga and Privigen

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. Immunoglobulin deficiencies
B. Immune/idiopathic thrombocytopenic purpura
C. Children with human immunodeficiency virus
D. Myasthenia gravis
E. Guillain-Barre syndrome
F. Chronic inflammatory demyelinating neuropathy (CIDP)
G. Dermatomyositis
H. Relapsing-remitting multiple sclerosis (RRMS)
I. Multifocal motor neuropathy (MMN)
J. Autoimmune retinopathy
K. Autoimmune mucocutaneous blistering diseases
    1. Pemphigus vulgaris
    2. Pemphigus foliaceus
    3. Bullous pemphigoid
    4. Mucous membrane pemphigoid (cicatricial pemphigoid)
    5. Epidermolysis bullosa acquisita
L. Chronic lymphocytic leukemia
M. Cytomegalovirus prophylaxis in bone marrow or stem cell transplantation
N. Desensitization before kidney transplantation
O. Antibody mediated kidney transplant rejection
P. Desensitization before heart transplantation
Q. Antibody mediated heart transplant rejection
R. Antibody mediated stem cell transplant rejection
S. Kawasaki disease

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

A. History and physical supporting physician rationale for treatment (current to within 12 months)
B. Physician's orders not more than 30 days from the date of service which specify the dose, frequency, route of administration, and duration
C. Office progress notes which clearly document the necessity of both initiation and continuation of IVIG
D. Applicable laboratory and procedure results
E. An accurate weight prior to each infusion as the dosage is based on milligrams per kilogram
F. Prior therapies failed or rationale for why such therapies are contraindicated
G. Medication administration records

III. CRITERIA FOR APPROVAL

A. Immunoglobulin deficiencies

Authorization of 6 months may be granted for treatment of immunoglobulin deficiencies when any of the following criteria is met:

1. Pretreatment IgG level < 200 mg/dL
2. Member has a clinical reason for requiring treatment before IgG level falls below 200 mg/dL

B. Immune/idiopathic thrombocytopenic purpura (ITP)

1. ITP in pregnancy: authorization of 6 months may be granted when all of the following criteria are met:
   a. Member is a pregnant woman who:
      i. Has previously delivered infants with autoimmune thrombocytopenia, or
      ii. Has platelet counts less than 75,000/μL during the current pregnancy, or
      iii. Past history of splenectomy
   b. At least one of the following criteria are met regarding prior treatment:
      i. Member has failed other therapy
      ii. Member has a contraindication to other therapy
      iii. Member has a rapidly progressive form of the disease
2. Acute ITP: authorization of 1 month may be granted when any of the following criteria is met:
   a. Member has a platelet count < 30,000/μL and IVIG is required to manage an acute bleeding episode
   b. IVIG is required to increase the member's platelet count prior to an invasive surgical procedure
   c. Member has a platelet count < 20,000/μL and is considered to be at risk for intracerebral hemorrhage
3. Chronic ITP, first-line treatment: authorization of 6 months may be granted when any the following criteria is met:
   a. Age < 18 years of age
   b. IVIG is used in combination with steroids to evoke a rapid platelet response or to avoid splenectomy
   c. Member has a contraindication to steroids
4. Chronic ITP, subsequent treatment: authorization of 6 months may be granted when any the following criteria is met:
   a. Member's platelet counts are persistently at or below 20,000/μL
   b. Member has had an inadequate response to both splenectomy and steroids

C. Children with human immunodeficiency virus

Authorization of 6 months may be granted for treatment of a child with human immunodeficiency virus when all of the following criteria are met:

1. Age < 13 years of age

2. CD4+ lymphocyte count ≥ 200/μL
3. Patient is clinically symptomatic or immunologically abnormal

D. Myasthenia gravis

Authorization of 6 months may be granted for treatment of myasthenia gravis when all of the following criteria are met:

1. Member has experienced rapid disease progression or other forms of treatment have failed or are contraindicated
2. If the condition improves with IVIG therapy, the prescriber will attempt to decrease and wean the IVIG dose or frequency of administration
3. If the condition does not improve in a quantitative way following initiation of IVIG therapy, the prescriber will discontinue the treatment

E. Guillain-Barre syndrome

Authorization of 1 month may be granted for treatment of Guillain-Barre syndrome when all of the following criteria are met:

1. Member has experienced rapid disease progression or other forms of treatment have failed or are contraindicated
2. If the condition improves with IVIG therapy, the prescriber will attempt to decrease and wean the IVIG dose or frequency of administration
3. If the condition does not improve in a quantitative way following initiation of IVIG therapy, the prescriber will discontinue the treatment

F. Chronic inflammatory demyelinating neuropathy (CIDP)

Authorization of 6 months may be granted for treatment of chronic inflammatory demyelinating neuropathy when all of the following criteria are met:

1. Consultation has occurred with a neurologist or rheumatologist who is an expert in the field of CIDP to validate the diagnosis and clarify the need for IVIG treatment
2. If IVIG is prescribed in a member with presumed CIDP that predominantly affects the sensory nerves and the goal of therapy is to control pain, the member must have had a measurable response to a therapeutic trial of prednisone.
3. Member has experienced rapid disease progression or other forms of treatment have failed or are contraindicated
4. If the condition improves with IVIG therapy, the prescriber will attempt to decrease and wean the IVIG dose or frequency of administration
5. If the condition does not improve in a quantitative way following initiation of IVIG therapy, the prescriber will discontinue the treatment

G. Dermatomyositis

Authorization of 6 months may be granted for treatment of dermatomyositis when all of the following criteria are met:

1. Other forms of treatment have failed or are contraindicated
2. If the condition improves with IVIG therapy, the prescriber will attempt to decrease and wean the IVIG dose or frequency of administration.
3. If the condition does not improve in a quantitative way following initiation of IVIG therapy, the prescriber will discontinue the treatment.

H. Relapsing-remitting multiple sclerosis

Authorization of 6 months may be granted for treatment of relapsing-remitting multiple sclerosis when all of the following criteria are met:

1. Other forms of treatment have failed or are contraindicated
2. If the condition improves with IVIG therapy, the prescriber will attempt to decrease and wean the IVIG dose or frequency of administration.
3. If the condition does not improve in a quantitative way following initiation of IVIG therapy, the prescriber will discontinue the treatment.

I. Multifocal motor neuropathy

Authorization of 6 months may be granted for treatment of multifocal motor neuropathy when all of the following criteria are met:

1. Consultation has occurred with a neurologist or rheumatologist who is an expert in the field of CIDP (and CIDP variants) to validate the diagnosis and clarify the need for IVIG treatment
2. Member has experienced rapid disease progression or other forms of treatment have failed or are contraindicated
3. If the condition improves with IVIG therapy, the prescriber will attempt to decrease and wean the IVIG dose or frequency of administration.
4. If the condition does not improve in a quantitative way following initiation of IVIG therapy, the prescriber will discontinue the treatment.

J. Autoimmune retinopathy

Authorization of 3 months may be granted for initial treatment of autoimmune retinopathy.

Authorization of 6 months may be granted for continued treatment of autoimmune retinopathy when the member has shown improvement within 3 months from start of IVIG treatment.

K. Autoimmune mucocutaneous blistering diseases

Authorization of 6 months may be granted for treatment of biopsy proven autoimmune mucocutaneous blistering diseases when all of the following criteria are met:

1. Member has one of the following diagnoses: pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid (cicatricial pemphigoid), or epidermolysis bullosa acquisita
2. At least one of the following criteria is met regarding prior treatment with conventional therapy:
   a. Member has failed conventional therapy
   b. Member has a contraindication to conventional therapy
   c. Member has rapidly progressive disease and a clinical response could not be affected quickly enough using conventional agents, and IVIG will be given in combination with conventional treatment
3. IVIG will be used for short-term control of the member's condition and will not be used as maintenance therapy

L. Chronic lymphocytic leukemia

Authorization of 6 months may be granted for members with chronic lymphocytic leukemia when all of the following criteria are met:

1. IgG level < 600 mg/dL or evidence of specific antibody deficiency
2. Member experiences recurrent bacterial infections

M. Cytomegalovirus prophylaxis in bone marrow or stem cell transplantation

Authorization of 6 months may be granted for members who is undergoing bone marrow or stem cell transplantation when all of the following criteria are met:

1. Age ≥ 20 years
2. Transplantation is for a Medicare covered indication

3. Member is cytomegalovirus seropositive before transplantation, or a donor is seropositive and the member is undergoing an allogeneic transplantation for a hematologic neoplasm.

N. Desensitization before kidney or heart transplantation
Authorization of 6 months may be granted for desensitization before kidney or heart transplantation.

O. Antibody-mediated transplant rejection of heart, kidney or stem cell
Authorization of 6 months may be granted for prevention and treatment of antibody-mediated transplant rejection of the heart, kidney or stem cell transplant.

P. Kawasaki disease
Authorization of 1 month may be granted for treatment of Kawasaki disease.

IV. REFERENCES

1. Immune Globulin Intravenous LCD (L34074) Version R11. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed June 7, 2022.
2. National Coverage Determination (NCD) for Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases (250.3- Version1). Accessed at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=158&ncdver=1&SearchType=Advanced&CoverageSelection=National&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&KeyWord=Immune+Globulin&KeyWordLookUp=Title&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAAAAAAA%3d%3d&. Accessed June 7, 2022.